

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sudhir V. Shah

Divisional

Application No.: 09/553,496

Group Art Unit: 1654

Filed: April 20, 2000

Examiner: Randall O. Winston

Confirmation No.:

Title: DIAGNOSIS AND TREATMENT OF HUMAN KIDNEY DISEASES

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| Date: <u>12/9/03</u> |
| EXPRESS MAIL LABEL NO. <u>EL 955641122 US</u> |

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☐ Copies of the cited references are enclosed.
 - ☐ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - ☒ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. 09/553,496, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.
 - ☒ The listed references, AL-AO, AY3, AZ3 and AR4, were cited in the International Search Report in a related foreign application, a copy of which was entered in prior Application No. 09/553,496.
 - ☒ The "concise explanation" requirement (non-English references) for reference AO under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☒ the English language abstract, a copy of which was entered in prior Application No. 09/553,496.

☒ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. 09/553,496, by Sudhir V. Shah, filed April 20, 2000, Docket No.: 2629.1003-003.

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

☐ A copy of each above-cited application, including the current claims, is enclosed.

☒ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. 09/553,496, to which priority under 35 U.S.C. 120 or 121 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated: December 9, 2003

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| PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION November 14, 2003 (Use several sheets if necessary) | ATTORNEY DOCKET NO. 2629.1003-010 | | DIVISIONAL APPLICATION NO. 09/553,496 | |
| | APPLICANT Sudhir V. Shah | | | |
| | FILING DATE | | CONFIRMATION NO. | GROUP 1654 |

| U.S. PATENT DOCUMENTS | | | | |
|-------------------------------|-------------|-----------------|----------------------------------|------------------------|
| EXAM- INER INI- TIAL | REF. NO. | DOCUMENT NUMBER | ISSUE DATE / PUBLICATION DATE | NAME |
| | AA | 5,047,421 | Sep 10, 1991 | Green |
| | AB | 5,721,209 | Feb 24, 1998 | Horwitz <i>et al.</i> |
| | AC | 5,811,127 | Sep 22, 1998 | Milstein <i>et al.</i> |
| | AD | 4,684,482 | Aug 4, 1987 | Green |
| | AE | | | |
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| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|-----|-----------------|------------|---------------|-----------------------|--|
| | | DOCUMENT NUMBER | DATE | COUNTRY | TRANSLATION YES NO | |
| | AL | WO 94/01770 A | 20 Jan 94 | PCT | X | |
| | AM | DE 40 08 323 A | 19 Sept 91 | Germany | X | |
| | AN | WO 00 13706 A | 16 Mar 00 | PCT (English) | | |
| | AO | WO 91 07956 A | 13 June 91 | PCT | | |
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| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | |
|------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| AR | Sumboonnanonda, A., <i>et al.</i> , “Renal tubular function in β -thalassemia”, <i>Pediatr Nephrol</i> , 12:280-283. | |
| AS | Ong-ajyooth, L., <i>et al.</i> , “Renal Function in Adult Beta-Thalassemia/Hb E Disease”, <i>Nephron</i> , 78:156-161 (1998). | |
| AT | Guasch, A., <i>et al.</i> , “Evidence that Microdeletions in the α Globin Gene Protect Against the Development of Sickle Cell Glomerulopathy in Humans”, <i>J Am Soc Nephrol</i> , 10:1014-1019 (1999). | |
| AU | Loebstein, R., <i>et al.</i> , “Diabetic Nephropathy in Hypertransfused Patients with β -Thalassemia”, <i>Diabetes Care</i> , 21(8):1306-1309 (1998). | |
| AV | Ongajyooth, L., <i>et al.</i> , “Glomerulonephritis in β -thalassemia Hb-E Disease: Clinical Manifestations, Histopathologic Studies and Outcome”, <i>J Med Assoc Thai</i> , 78(3):119-126 (1995). | |
| AW | Aoki, R.Y., <i>et al.</i> , “Microalbuminuria in Sickle Cell Disease”, <i>Brazilian J Med Biol Res</i> , 23:1103-1106 (1990). | |
| AX | Katopodis, K.P., <i>et al.</i> , “Renal Abnormalities in Patients with Sickle Cell-Beta Thalassemia”, <i>Journal of Nephrology</i> , 10(3):163-167 (1997). | |
| AY | Pham, P.-T.T., <i>et al.</i> , “Renal abnormalities in sickle cell disease”, <i>Kidney International</i> , 57:1-8 (2000). | |
| AZ | Kontoghiorghe, G.J., <i>et al.</i> , “Simple Synthesis of the Potent Iron Chelators 1-Alkyl-3-hydroxy-2-methylpyrid-4-ones”, <i>Inorganica Chimica Acta.</i> , 136:L11-L12 (1987). | |
| AR2 | Falk, R.J., <i>et al.</i> , “Prevalence and Pathologic Features of Sickle Cell Nephropathy and Response to Inhibition of Angiotensin-Converting Enzyme”, <i>The New England Journal of Medicine</i> , 326(14):910-915 (1992). | |
| AS2 | Guasch, A., <i>et al.</i> , “Sickle cell anemia causes a distinct pattern of glomerular dysfunction”, <i>Kidney International</i> , 51:826-833 (1997). | |
| AT2 | Cianciulli, P., <i>et al.</i> , “Early detection of nephrotoxic effects in thalassemic patients receiving desferrioxamine therapy”, <i>Kidney International</i> , 46:467-470 (1994). | |
| AU2 | Ueda, N., <i>et al.</i> , “Role of ‘catalytic’ iron in an animal model of minimal change nephrotic syndrome”, <i>Kidney International</i> , 49:370-373 (1996). | |

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| | FILING DATE | CONFIRMATION NO. | GROUP 1654 | |

| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | |
|------------------------------------------------------------------------|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | AV2 | Savill, J., <i>et al.</i> , "Mechanisms of glomerular injury". In "Oxford Textbook of Clinical Nephrology," 2 nd ed., pages 404-439, eds., Davidson, A.M., <i>et al.</i> , Oxford Univ. Press (1998). |
| | AW2 | Ueda, N., <i>et al.</i> , " <i>In Vivo</i> Evidence for a Role of Reactive Oxygen Metabolites in Glomerular Disease", <i>Kidney: A Current Survey of World Literature</i> , 6:143-146 (1997). |
| | AX2 | Boyce, N.W., <i>et al.</i> , "Hydroxyl radical mediation of immune renal injury by desferrioxamine", <i>Kidney International</i> , 30:813-817 (1986). |
| | AY2 | Baliga, R., <i>et al.</i> , "Kidney Iron Status in Passive Heymann Nephritis and the Effect of an Iron-Deficient Diet", <i>J Am Soc Nephrol</i> , 7(8):1183-1188 (1996). |
| | AZ2 | Shah, S.V., "Evidence suggesting a role for hydroxyl radical in passive Heymann nephritis in rats", <i>The American Physiological Society</i> , F337-F344(1988). |
| | AR3 | Thakur, V., <i>et al.</i> , "Evidence suggesting a role for hydroxyl radical in puromycin aminonucleoside-induced proteinuria", <i>Kidney International</i> , 34:494-499 (1988). |
| | AS3 | Nankivell, B.J., <i>et al.</i> , "The Role of Tubular Iron Accumulation in the Remnant Kidney", <i>J Am Soc Nephrol</i> , 4(8):1598-1607 (1994). |
| | AT3 | Alfrey, A.C., <i>et al.</i> , "Role of iron in the tubulo-interstitial injury in nephrotoxic serum nephritis", <i>Kidney International</i> , 36:753-759 (1989). |
| | AU3 | El Nahas, A.M., "Mechanisms of experimental and clinical renal scarring" In: "Oxford Textbook of Clinical Nephrology", 2 nd ed., pages 1749-1788, eds., Davidson, A.M., <i>et al.</i> , Oxford Univ. Press (1998). |
| | AV3 | Howard R.L., <i>et al.</i> , "Urinary albumin, transferrin and iron excretion in diabetic patients", <i>International Society of Nephrology</i> , 40:923-926 (1991). |
| | AW3 | Olivieri, N.F., <i>et al.</i> , "Iron-Chelation Therapy with Oral Deferiprone in Patients with Thalassemia Major", <i>The New England Journal of Medicine</i> , 918-922 (1995). |
| | AX3 | Alfrey A.C., "Toxicity of tubule fluid iron in the nephrotic syndrome", <i>American Journal of Physiology</i> , 263(4):F637-F641 (1992). |
| | AY3 | Wu,Z-L, <i>et al.</i> , "Iron Loading Enhances Susceptibility to Renal Ischemia in Rats," <i>Renal Failure</i> 16(4):471-480 (1994). |

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